DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: PATANOL™
Docket No. 97E-0108

MAY 20 1997

#32

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,116,863, filed by Alcon Laboratories, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for PATANOL™, the human drug product claimed by the patent.

The total length of the regulatory review period for PATANOL™ is 1,064 days. Of this time, 739 days occurred during the testing phase and 325 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 21, 1994.

   The applicant claims January 20, 1994, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 1994, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505 of the Federal Food, Drug, and Cosmetic Act: January 29, 1996.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for PATANOL™ (NDA 20-688) was initially submitted on January 29, 1996.

3. The date the application was approved: December 18, 1996.

   FDA has verified the applicant's claim that NDA 20-688 was approved on December 18, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Patrick M. Ryan
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